NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Guangdong Nuokang Medical Technology Co., Ltd

Model Tested: KN95 Protective Face Mask

Date Tested: November 5, 2020

These findings pertain to the Guangdong Nuokang Medical Technology Co., Ltd., model KN95 Protective Face Mask. The packaging for this product indicates that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator).

Ten respirators were submitted for evaluation. The samples were tested using a modified version of NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059. This modified assessment plan can be found here.

No certificate of approval was provided with the samples received; therefore, the authenticity of the claims cannot be validated.

The maximum and minimum filter efficiency was 61.60% and 34.30%, respectively. All ten respirators measured less than 95%.

While the above-listed product classification has similar performance requirements to NIOSH-approved devices, NIOSH does not have knowledge about the sustained manufacturer quality system and product quality control for these products. NIOSH also does not have knowledge about the product's handling and exposures after leaving its manufacturer's control.

In addition, this product is an ear loop design. Currently, there are no NIOSH-approved products with ear loops; NIOSH-approved N95s have head bands. Furthermore, limited assessment of ear loop designs, indicate difficulty achieving a proper fit. While filter efficiency shows how well the filter media performs, users must ensure a proper fit is achieved.

This assessment is not a part of the NIOSH respirator approval process and will in no way lead to or preclude NIOSH approval through the official approval process. This assessment was developed as an assessment of the filter efficiency for those respirators represented as certified by an international certification authority, other than NIOSH, to support the availability of respiratory protection to US healthcare workers due to the respirator shortage associated with COVID-19. Only particulate filter efficiency was assessed.

The results provided in this letter are specific to the subset of samples that were provided to NPPTL for evaluation.

These results will be used to update the CDC guidance for <u>Crisis Capacity Strategies (during known shortages)</u>.

Evaluation of International Respirators



Pictures have been added to the

end of this report.

Test: Modified TEB-APR-STP-0059

Date Tested: November 5, 2020

Report Prepared: November 5, 2020

Manufacturer: Guangdong Nuokang Medical Technology Co., Ltd

Item Tested: KN95 Protective Face Mask

Country of Certification: China (GB2626-2006)

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	9.6	40.1	40.1	59.90
2	85	10.5	45.7	45.7	54.30
3	85	8.2	42.9	42.9	57.10
4	85	13.0	38.4	38.4	61.60
5	85	9.1	43.2	43.2	56.80
6	85	10.1	41.7	41.7	58.30
7	85	9.1	42.9	42.9	57.10
8	85	10.7	42.6	42.6	57.40
9	85	7.6	65.7	65.7	34.30
10	85	7.6	64.1	64.1	35.90
Minimum Filter Efficiency: 34.30%			Maximum Filter Efficiency: 61.60%		

- The test method utilized in this assessment is not the NIOSH standard test procedure that is used for certification of
 respirators. Respirators assessed to this modified test plan do not meet the requirements of STP-0059, and
 therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059.
- Respirators tested may not be representative of all respirators with the same certification mark. NIOSH has no control over suppliers and distributors of respirators certified by other national or international parties.
- This assessment is not a confirmation that it conforms with any or all of its specifications in accordance with its certification mark.
- This assessment was not a part of the NIOSH approval program. These results do not imply nor preclude a future approval through the NIOSH respirator approval program.







KN95 5-LAYER NON-WOVEN PROTECTIVE FACE MASK

Anti-bacteria, anti-virus

METHOD OF USE









- 101 The nose clip part is facing up, the side without nose clip is facing the face, and the ear straps are pulled on each hand;
- 02 Face the mask against the chin first, and pull the ear-band back to the ear and hang it on the ear until
- Place the fingers of both hands in the middle of the nose clip and press inwardly according to the shape of the nose bridge th conform to the shape of the nose bridge;
- O4. Face the mask against the chin first, and pull the ear-band back to the ear and hang it on the ear until it feels feels comfortable;
- 05 Put your hands on your face when using, and check the tightness with your face.

Manufacturer: Guangdong Nuokang Medical Technology Co., Ltd

ADDRESS: NO18, Housha Road, Dongguan City, Guangdong Province, china Contact: +86-769-81266677

NPPTL COVID-19 Response: International Respirator Assessment





检验合格证 INSPECTION CERTIFICATE

产品名称: 五层 KN95 非医用防护口罩

PRODUCT: FIVE LAYERS KN95 PROTECTIVE FACE MASK

产品规格/型号: 105*160MM

SIZE: 105*160MM

执行行业标准: GB2626-2006

EXECUTIVE STANDARD: GB2626-2006

主要原材料 MAIN RAW MATERIALS

外层: 白色 PP 无纺布 (两层)

OUTER LAYER: WHITE PP NON-WOVEN FABRIC(DOUBLE LAYERS)

中层: 高效过滤熔喷布

INNER LAYER: HIGH EFFICIENCY FILTER MELT-BLOWN FABRIC

内层: 白色 PP 无纺布 (两层)

INNER LAYER: WHITE PP NON-WOVEN FABRIC(DOUBLE LAYERS)

生产批次: KJ20200420 LOT NO.: KJ20200420

生产日期: 2020年4月18日 PRODUCTION DATE: 2020/4/18

保质期: 24 个月 EXPIRED: 24 MONTHS

生产厂家:广东省诺康医疗科技有限公司

MANUFACTURER: GUANGDONG NUOKANG MEDICAL TECHNOLOGY CO.,LTD.

厂家地址: 广东省东莞市厚街镇厚街环湖路 10 号 14 号 207 室

ADDRESS: Room 207, Building 14, No. 10, Houjie Huanhu Road, Houjie Town, Dongguan, Guangdong

Province.

使用说明:

1. 本产品只适用于日常生活空气污染环境下滤除颗粒物佩戴。
This product is only suitable for filtering particles in the air polluted environment of daily life.

2. 检查正确口罩包装完好无损。

Please check if the mask package is intact.

3. 佩戴口罩应及时更换,不建议长期使用。

Recommend replacing the mask regularly, don't use if for long term.

4. 佩戴过程中如出现不适或不良反应,建议停止使用。

If there is discomfort or adverse reaction, it is recommended to stop using.

5. 产品应储存在干燥、通风、无腐蚀性气体的环境中。

The product shall be stored in dry, ventilated and non corrosive gas environment.

6. 推荐使用时间 4 小时。

Recommended wearing time is for 4 hours.









